

REMARKS

The Official Action of June 23, 2004, and the prior art cited and relied upon therein have been carefully reviewed. The claims in the application remain as claims 9-12, and these claims define patentable (novel and unobvious) subject matter warranting their allowance. Accordingly, applicant respectfully requests favorable reconsideration and allowance.

Some small amendments have been made in claim 9 above. The recitation added to lines 4 and 5 merely adds something which was previously intended and also implicit. The amendment at line 6 is really no change but is made merely to make consistent in form throughout the claims the presentation of ranges by consistent use of the hyphen in place of the word "to". No change in scope is made or intended.

Claims 9-12 have been rejected under §103 as obvious from Yokoi et al JP '724 (Yokoi) in view of Ogawa JP 11-228439A, reference R, Noevir KK (Ogawa). This rejection is respectfully traversed.

Claim 9 calls for a cosmetic composition which includes (1) a protease in an amount of 0.1-5% by weight,

which protease is extracted from fruit bodies or mycelia of basidiomycete and has the activity of decomposing cells, and (2) a culture supernatant of lactic acid bacteria in an amount of 10-50% by weight, which is obtained after removing bacterial cells from a culture filtrate of lactic acid bacteria obtained by culturing such bacteria. A key feature of claim 9 lies in the fact that the protease used has an action for decomposing cells.

Such protease, which has such a cell-decomposing action or activity, is an enzyme extracted from the basidiomycete in a state in which that action or activity is maintained. The extraction is achieved by use of a buffer with a pH close to that which is optimal for the desired enzyme, as described for example in applicant's specification at page 6, line 11 to page 7, line 4. Thus, at page 6, lines 16 and 17, it is indicated that it desirable to extract "with buffers of their respective pHs."

As regards the aforementioned cell-decomposing action or activity of such protease used in the present invention, applicant's specification states as follows at page 8, commencing with line 11:

With experiments by the present invention, etc, when it was applied to the chloasma (dead cell) on the arm, it exhibited such high lysis effects that the chloasma was reduced in size and also color in several days. ...

And, further at page 8, lines 17-21:

With the cosmetic of the present invention, pigmented old skin cells and dead cells are decomposed by the foregoing proteases to remove the chloasmata, freckles, lentigines, and the like, wherein the enzyme actions of the protease are utilized.

The cosmetic of the present invention thus has the advantageous effect that the protease decomposes pigmented old skin cells and dead cells to remove the chloasmata, freckles, and lentigines by its cell-decomposing action, as described in the specification at page 8, lines 17 to 21.

The culture supernatant used in applicant's cosmetic also has the advantageous effect that it stabilizes the enzyme action of the protease, which provides a new combination effect, together with the further advantageous effect that it maintains the moisture of the skin and promotes new formation of skin cells by the vitamins, minerals and so on included within it, as described in the specification at page 12, lines 15 to 21.

As described above, because the protease acts directly on the pigmented cells to decompose and remove them and, at the same time, the new formation of skin cells is promoted by the culture supernatant, the claimed cosmetic of the present invention has the advantageous effect that

pigmented skin (freckles and so on) can be removed in a short time. For example, table 14 shows a case (example 15) in which such an effect appeared within only seven days.

Set against these facts are the following : (1) a cosmetic for skin including a culture supernatant of lactic acid bacteria disclosed in Yokoi (the culture supernatant is separated from a culture obtained by culturing the lactic acid bacteria by use of culture media such as the human milk, cow milk, and goat milk, and so on, as described at column 2, paragraph [0008] of Yokoi; and (2) an external preparation for skin including Agaricus fungus-mycelium extract disclosed in Ogawa.

However, these cited reference do not disclose or suggest a protease having an action for decomposing cells as in the present invention. While Ogawa discloses a cosmetic composition including an extract of mycelium culture filtrate of Agaricus blazei, Ogawa does not explicitly or inherently disclose the use of a protease extracted from fruit bodies or mycelia of basidiomycete having a cell-decomposing activity as claimed.

Thus, in Ogawa, the Agarius fungus-mycelium extract is prepared such as by immersion at ambient temperatures or by a vapor distillation method using a utility polar solvent such

as water, monohydric alcohol or the like, as described on page 3, paragraph [0013] and paragraph [0014], in the Ogawa specification. A rough (machine) translation of portions of the these paragraphs follow:

[0013] ... For example, alcohols, such as water, ethanol, a methanol, isoproponal, isobutanol, n-hexanol, methyl amyl alcohol, 2-ethyl butanol, and n-octyl alcohol, A glycerol, ethylene glycol, ethylene glycol monomethyl ether, ethylene glycol monoethyl ether, propylene glycol, propylene glycol monomethyl ether, the propylene glycol monoethyl ether, triethylene glycol, 1, One sort of solvents or two or more sorts of mixed solvents which are chosen from polyhydric alcohol, such as 3-butylene glycol and hexylene glycol, or the derivative of those can be used. Moreover, mineral, a surfactant, etc. may be added and used for a polar solvent. Also in these polar solvents, the solvent which added mineral salt and a surfactant is preferably used for one sort of solvents chosen from ethanol, a methanol, 1,3-butylene glycol, and water or two or more sorts of mixed solvents, and these solvents.

[0014] The approach of furthermore extracting under a room temperature as the extract approach using distillation which is made to carry out impregnation and is extracted, such as an approach and steam distillation, in the condition of having cooled or warmed, and raw agaricus -- a mushroom-- the milling process which squeezes a mycelium directly and obtains an extract illustrates -- having -- these approaches -- independent -- or it extracts combining two or more sorts.

And paragraph [0015] appears to suggest an extraction temperature of up to the boiling point of the solvent (or

possibly up to 5°C below the boiling point of the solvent), the text of the machine translation stating: "..., as for extract temperature, it is convenient under ordinary pressure to consider as the range below the boiling point of a solvent from 5°C,...."

Generally, when an enzyme is extracted, it is necessary to carry out the extraction under conditions which do not cause a loss in the desired activity. Therefore, adjustment for pH, selection of an extraction solvent, setting of the extraction temperature or the like must be carried out. However, Ogawa does not disclose specific conditions or conditions which would result in applicant's specific protease, and Ogawa does not disclose the need or search for a protease which has sell decomposing activity.

When the extraction is merely carried out using water, as shown in Ogawa, there is a possibility that the activity of the protease is reduced or lost. When the extraction is carried out by vapor distillation, as described above, the activity of the protease needed for use in the present invention is lost through heating at high temperature. Consequently, there is no suggestion of obtaining or using the protease necessary for the present invention in the cited reference.

Meanwhile, it is disclosed in paragraph [0006] of Ogawa that the external preparation for skin activates dermal fibrous tissue cells, thereby preventing aging symptoms of the skin and improving the skin. However, Ogawa does not disclose the use of applicant's protease or the effects of such protease. Accordingly, Ogawa cannot anticipate the effect of directly decomposing the pigmented cells as in the present invention. Therefore, even if the proposed combination were obvious, such combination would not correspond to the claimed subject matter.

Referring to MPEP 2143 and the following sections 2143.01 through 2143.03, applicant respectfully submits that the requirements for establishing a *prima facie* case of obviousness do not exist. Applicant has already pointed out above that Ogawa does not explicitly or inherently provide the protease which is a requirement of the present invention, and therefore the third requirement for a *prima facie* case of obviousness, i.e. that the references in combination must teach or suggest all the claimed features, does not exist (MPEP 2143.03).

Applicant also respectfully submits that the second requirement to establish a *prima facie* obviousness also does not exist, i.e. the requirement that there must be a

reasonable expectation of obtaining applicant's results (MPEP 2143.02). It is very clear that **neither** reference suggests applicant's results, and therefore no possible combination of these references could suggest applicant's results. The prior art does not provide any reasonable expectation of what applicant's composition provides as pointed out in applicant's specification, quoted above.

For the reasons pointed out above, claim 9 defines novel and unobvious subject matter under §§102 and 103, and therefore the rejection should be withdrawn and claim 9 allowed. Claims 10-12 depend from and incorporate the subject matter of claim 9, and therefore they also are patentable over the prior art for the reasons pointed out above.

Applicant wishes to add some additional remarks with respect to the bottom paragraph on page 3 of the Official Action. This paragraph seems to suggest that so-called process limitations may be ignored, but this is not correct. All recitations which appear in a claim must be given consideration, and that is fundamental patent law. Even true product-by-process language may well serve to define a product by characterizing that product by virtue of some particular property or properties given to that product due to the process by which it is made. Applicant respectfully notes *In*

re Luck et al, 177 USPQ 523, 525 (CCPA 1973), wherein the Court stated:

..., it is well established that product claims may include process steps to wholly or partially define the claimed product. See *In re Brown*, ... 173 USPQ 685, 688 (1972), and the cases cited therein. To the extent that these process limitations distinguish the product, over the prior art, **they must be given the same consideration as traditional product characteristics.**

(italics in original; other emphasis added)

In the present case, any process recitations appearing in claim 9 characterize the product for the reasons explained in detail above.

But applicant does not even agree that claim 9 contains any process recitations. Thus, language of the general type appearing in claim 9 has been held to be proper product language. In this regard, attention is respectfully invited to *In re Steppan et al*, 156 USPQ 143, 147, wherein claim 25, rejected as being an improper product-by-process claim, recited:

25. An acid phosphate of a condensation product of....

The appellants argued that "condensation product" merely defined "what the acid phosphate is". The Court held (page 148) claim 25

... to be a product claim sufficiently definitive to achieve the purposes for which it was drafted, i.e., to particularly point out and distinctly claim appellants'

invention, and not a "product by process" claim per se, as we understand the meaning of those terms.

In an analogous case, *In re Garnero*, 162 USPQ 221, 223, the CCPA held that "interbonded to one another by interfusion" is capable of being construed as a structural recitation just as are terms such as "intermixed", "ground in place", "press fitted", "etched", and "welded".

Attention is also invited to *In re Moore et al*, 169 USPQ 236, 237, 239 (CCPA 1971), where the criticized language was:

A mixture of highly fluorinated alkyladamantanes prepared by fluorinating and alkyl adamantine.

The Court held that the claims in question were not product-by-process claims.

Another precedential decision which should be considered is *In re Swinehart et al*, 169 USPQ 226, where the CCPA emphasized that an applicant should be given discretion in the manner in which he sets forth his invention. In the *Swinehart* case, the composition was recited as "being a solidified melt of two components...."

The language which appears in claim 9 is used to characterize the product which is what applicant is claiming (not the process). Such product is novel and would not have been obvious to the person of ordinary skill in the art, at

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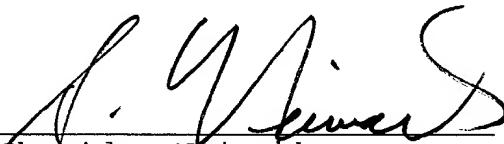
the time the present invention was made, from a consideration of the two citations.

Applicant believes that all issues have been addressed and resolved above, whereby the rejection of record should be withdrawn and the claims allowed. Such are respectfully requested.

Respectfully submitted,

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